by SDS-PAGE, and wherein said antigen does not cross-react immunologically with prostate-specific antigen.

## REMARKS

The instant application relates to novel tumor-associated antigens, see page 24, second full paragraph. The antigen is one that under normal circumstances does not elicit a humoral response. However, when administered with a proliferation-incompetent cell and a cytokine, the host raises a humoral response to the tumor antigen.

I. On page 2 of the Office Action, claims 23-34 were rejected under 35 U.S.C. § 112, first paragraph for an alleged want of enablement.

The rejection is traversed for the following reasons.

The instant invention relates to a method similar to that which has been found patentable, see Dranoff et al. discussed hereinbelow. The instant specification teaches how to make and how to use the cells, constructs and other materials of interest in a fully enabling fashion, especially when viewed in the context of the state of the art.

In particular, the instant application provides a thorough teaching of how to render a cell proliferation incompetent. Moreover, the instant invention teaches administration of cytokine. For example, the cancer cell can be transformed using suitable vectors to express cytokine. Otherwise, a second cell that is administered together with a tumor cell can be transformed to express cytokine. The instant application teaches a variety of ways of administering the composition of interest.

The instant application also provides a thorough teaching of how to identify an antigen of interest, namely, one that does not elicit a humoral response under normal circumstances but is immunogenic when administered with a proliferation-incompetent cell and a cytokine.

The methods for propagating cells, obtaining cytokine and administering the vaccine of interest are well detailed in the instant specification, and are well available to one of ordinary skill in the art.

The working examples teach how to identify such novel antigens and how to practice the claimed invention.

The instant application clearly directs the artisan to identify the tumor antigens of interest and provides a level of predictability such that an artisan has a reasonable expectation of successfully identifying the antigens of interest. Once identified, the instant application clearly sets forth use of the vaccine of interest for use in a patient with cancer.

The instant invention is in practice in clinical trials. The vaccine as constructed based on the teachings of the instant specification and administered as taught in the instant specification has proven successful in controlling prostate cancer development. Other vaccines of interest have been successfully used in clinical trials relating to treatment of lung cancer, pancreatic cancer, multiple myeloma and leukemia. The trials are at the Phase II stage and enrollment for Phase III trials is progressing.

Thus, the instant invention clearly is enabled. The Examiner has not made a prima facie case of non-enablement and the rejection must be removed.

II. In item 10 on page 5 of the Office Action, claims 23-34 were rejected under 35 U.S.C. § 102(b) over the Dranoff et al. patent.

The rejection is traversed for the following reasons.

As recited in base claim 23, the instant invention relates to particular tumor-associated antigens which alone does not stimulate a humoral response, but when administered with a proliferation-incompetent cell in the presence of a cytokine, is effectively immunogenic and the host is able to respond to that tumor-associated antigen, including, for example, generating antibody thereto.

The Dranoff et al. patent does not teach the claimed invention and thus, anticipation does not lie. Accordingly, withdrawal of the rejection is in order.

III. Beginning at the bottom of page 5 of the Office Action, claims 23-29 and 30-34 were rejected under 35 U.S.C. § 102(a) over WO98/04282.

The rejection is traversed for the following reasons.

As taught hereinabove, the instant invention relates to antigens to which the host does not react but for the concomitant administration of a proliferation-incompetent cell and cytokine.

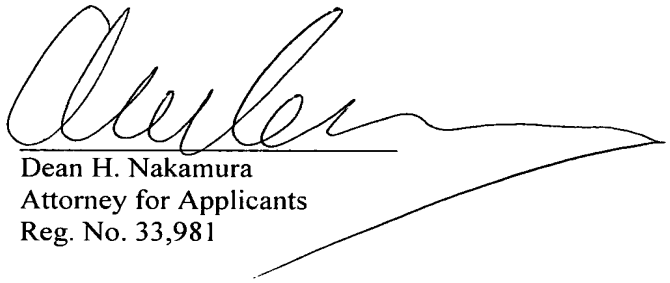
On the other hand, the '282 application relates to tumor antigens that are recognized by the host. For example, as noted at lines 31 and 32 on page 10 of the '282 application, the vaccines are useful even though the tumor cells are poorly immunogenic. An immunogenic antigen is different from one that is not immunogenic but for the simultaneous administration of proliferation-incompetent cells and cytokine.

Therefore, the '282 application does not teach the claimed invention. Because anticipation does not exist, the rejection should be removed.

## CONCLUSION

The instant application is in condition for allowance. Reconsideration, withdrawal of the rejections and early indication of allowance are solicited earnestly. If any questions remain unresolved, the Examiner is urged to contact the undersigned at the local exchange noted hereinbelow. The Commissioner hereby is authorized to charge or to credit any shortage or surplus to Deposit Account No. 18-2220.

Respectfully submitted,



Dean H. Nakamura
Attorney for Applicants
Reg. No. 33,981

Roylance, Abrams, Berdo
& Goodman L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036-2680
(202) 659-9076

Dated: 28 February 2002

23. A vaccine comprising a nucleic acid encoding a tumor-associated antigen, wherein said tumor-associated antigen alone does not stimulate a humoral response, and said tumor-associated antigen stimulates a humoral response when exposed on a proliferation-incompetent cell in the presence of a cytokine[.

30. The vaccine of claim 23], wherein said antigen has a molecular weight selected from the group consisting of 250 kD, 160 kD, 150 kD, 130 kD, 105 kD, 60 kD, 32 kD, 31 kD, 27 kD, 26 kD, 14 kD and 12 kD, as determined by SDS-PAGE, and wherein said antigen does not cross-react immunologically with prostate-specific antigen.